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January 16, 2004

HAND DELIVERY

Document Control Office
Information Management Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
Room B-102
1301 Constitution Ave., N.W.
Washington, D.C.

Attn: TSCA § 4



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CITR 600

Re: **Albaugh, Inc. Protocol – TSCA Section 4**
Response to EPA Letter Dated October 16, 2003

Dear Sir or Madam:

I write on behalf of Albaugh, Inc. (Albaugh) in response to the Agency's letter of October 16, 2003 regarding the proposed protocol submitted by Albaugh to EPA on January 22, 2003. Albaugh's response to EPA's letter is set forth below and certain amendments to the proposed protocol also are attached.

As an initial matter, Albaugh is disappointed that EPA's October 16, 2003, letter takes the position that Albaugh must proceed with analysis of the retained samples of the subject chemical notwithstanding the fact that Albaugh is no longer manufacturing (i.e., importing), processing, distributing or using the test chemical in commerce in the United States. While Albaugh continues to cooperate with EPA on this issue and has offered to complete the protocol for future use by EPA (if and when the test chemical is ever in the future imported/manufactured in the U.S.), Albaugh continues to believe that it is unnecessary to proceed with an analysis of the retained samples and that any resulting test data will be of questionable value.

Indeed, as a practical matter, any possible objective of the Test Rule has already been fulfilled in that the test substance is no longer being manufactured or imported by Albaugh in or into the United States and is no longer in commerce in the United States.

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Albaugh has further informed EPA, on several occasions, of its willingness to formalize its commitment not to re-initiate any manufacturing or importation of the test substance in the United States, without first complying with all of the requirements of the Test Rule.

As further discussed in this letter, the testing of the available samples of the test substance is not likely to produce useful or reliable data, which is the purpose of the Test Rule to generate, and any policy reasons for the test rule have essentially been fulfilled by virtue of the removal of the test substance from commerce in the United States. Therefore, Albaugh requests EPA to reconsider its position on the necessity and usefulness of having Albaugh analyze the retained test samples.

With respect to the specific issues raised in EPA's October 16, 2003 letter, Albaugh notes, at the outset, that the Agency requests certain information and modifications to the proposed protocol to which Albaugh cannot fully respond. This is because certain of the requests are dependent on information that Albaugh does not have and/or apparently are based on the assumption that additional samples of the test substance are available (as explained below, the proposed protocol submitted to EPA on January 22, 2003 is based on the seven samples of the test substance that are the only samples in Albaugh's possession). Thus, while Albaugh responds to the best of its ability to EPA's October 16, 2003, letter, it cannot, as it has previously advised EPA, respond to requests seeking information it does not have, nor submit protocol modifications that are dependent on additional samples that are not available.¹

For the above reasons, Albaugh respectfully requests EPA to accept the proposed protocols submitted to EPA on January 22, 2003, with the additional information set forth below, including the attachments and the amended portions of the protocols appended to this letter.

RESPONSES TO OCTOBER 16, 2003 LETTER

1. "Sample collection data (date, time, etc.)."

Response: Albaugh is not able to provide the requested information for all of the seven retained chemical samples in its possession. However, the labels on the retained test samples identified by Blackman Uhler as numbers 5 and 7 do have some of this

¹ Indeed, it is a basic tenet of administrative law that "impossible requirements imposed by an agency are perforce unreasonable: 'Conditions imposed by [the] order are . . . unreasonable by virtue of being impossible to meet.'" *Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 940 (D.C. Cir. 1991), citing *D.C. Transit Sys., Inc. v. Washington Metropolitan Area Transit Comm'n*, 466 F.2d 394, 402 (D.C. Cir.), cert. denied, 409 U.S. 1086 (1972).

information. In particular, the label on retained sample number 5 indicates that it was collected on August 10, 1999 at 0300 hours. The label on retained sample number 7 indicates that it was collected on September 7, 2000. For EPA's information, a photograph of all seven of the test chemicals in Albaugh's possession at Albaugh's plant in St. Joseph, Missouri is attached to this letter (Att. 1).

2. "If and/or how the top and bottom of drum samples were composited."

Response: To the best of Albaugh's knowledge, the samples in Albaugh's possession are not composites of samples taken from the top and bottom of drums. Rather, the samples were collected as a single sample from the drum.

3. "Number of samples (seven random samples from each supplier for a total of fourteen)."

Response: The information that Albaugh previously provided is correct. Albaugh has custody of seven samples of the test chemical that were collected by Blackman Uhler. At the time of Albaugh's June 21, 2001 correspondence to Ms. Pozda ("Albaugh letter"), Albaugh was informed by its former supplier in China that *the supplier* was in possession of 10 additional samples that it had collected *prior* to shipment to Blackman Uhler. Such 10 additional samples at all times were located in the People's Republic of China in the custody of the former supplier. While Albaugh requested the supplier to retain the samples pending further instructions (see Albaugh letter at p. 3), the Chinese supplier recently informed Albaugh that it no longer retains such samples. Albaugh therefore only has custody of three samples of the test substance from the Chinese supplier.

4. "Albaugh must provide detailed information about all samples taken, the disposition of the unavailable samples and provide an explanation as to why only a total of seven samples from selected batches are proposed to be tested."

Response: With respect to the manner in which the samples were taken, Albaugh does not believe that there is any additional information in existence regarding the sample collection process, with the exception of the information reflected in this letter and the documents appended hereto, including a copy of Blackman Uhler's "DCP Drum Sampling Procedure" and the amendment to section 7.3.3. of the proposed protocol described below. Therefore, in addition to the information set forth in this letter and related attachments, Albaugh respectfully refers EPA back to the sample collection process set forth in Section 7.3 ("Sampling") of the proposed protocol submitted to EPA on January 22, 2003.

In this regard, it is important to note that, at the time the samples were collected by Blackman Uhler, there was no intention that they would be considered for use by EPA for purposes of analysis under the Test Rule; rather, they were collected in the ordinary course of business by Blackman Uhler for general quality control and quality

assurance purposes and not for purposes of analysis under TSCA section 4. The disposition of the samples retained by its former supplier in China about which Albaugh was previously informed is disclosed above; Albaugh does not have any more information with regard to the disposition of those samples.

As to why only a total of seven samples from the selected batches are identified for testing, as explained above, those are the only samples of the test substance known to exist. There are no stockpiles of the test substance from which additional samples can be collected. The test substance is no longer being manufactured by Albaugh's former suppliers; hence, additional samples cannot be obtained from those suppliers. If EPA proceeds in requiring Albaugh to implement the test rule, these are the only known samples that can be subjected to testing.

5. "Information must be provided to document how the proposed samples are 'representative' of the imported products."

Response: To the extent that EPA needs information to demonstrate that the retained samples are "representative" of the "imported products," Albaugh can only offer that the samples were deemed representative by Blackman Uhler for purposes of quality assurance and quality control (see section 7.3.2. of the proposed protocol). The toll manufacturer, Blackman Uhler, deemed the retained samples to be representative for such purposes by virtue of the agitation of the test substance that occurred when the drums containing the liquified substance were removed from the steam cabinet. Attached hereto is an amendment to section 7.3.3 of the proposed protocol referencing the agitation that occurred when the drums were removed from the steam cabinet (Att. 2, signed in counterpart). Again, as noted above, at the time the samples were collected by Blackman Uhler, there was no intention that they would be considered for use by EPA for purposes of analysis under the Test Rule. Rather, they were collected in the ordinary course of business by Blackman Uhler for general quality control and quality assurance purposes and not for purposes of analysis under TSCA section 4. Albaugh makes no claim that the samples as collected are representative of the test substance for purposes of implementing the Test Rule; rather, Albaugh has identified these samples because they are the only samples of the test substance that are known to exist and, hence, the only samples that can possibly be subjected to the Test Rule.

It is for the above reason that Albaugh continues to question the value of requiring the analysis of the retained samples under the Test Rule. Because there is limited information available regarding the "representativeness" of the retained samples in comparison to the imported samples, the test results will likely yield little, if any, useful information regarding the presence of dioxins in the test substance. This would appear to defeat the very purpose of the test rule. See also "Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by the Environmental Protection Agency" (Oct. 2002) at 15, which defines "quality" of information according to whether, among other things, the information "as a matter of substance, is accurate, reliable and unbiased" and is "useful" to the intended users. It

seems clear that any results derived from testing these samples -- in light of their limited number, the fact that they are not from consecutive batches, the limited amount of information regarding how they were collected and handled, the amount of time that has passed since they were collected, etc. -- cannot yield reliable or useful data regarding the presence and/or quantity of dioxins in the test substance.

6. "Because samples have already been taken, the protocol must state how samples were taken, plus if and how the top and bottom samples were composited ... Sample collection data (e.g. date, manufacturer, batch, etc.) must be provided for the samples that are selected for testing. Justification for such selection is necessary as well."

Response: With respect to the request that the protocol "must state how the samples were taken," Albaugh is amending section 7.3.3 of the proposed protocol to reflect the "agitation" process that occurred before the samples were collected (see attached protocol amendment). Otherwise, Albaugh is not aware of any additional information from Blackman Uhler describing the sample collection process other than that currently described in the protocol and this letter. As noted above in response to question number 2, to the best of Albaugh's knowledge, the retained samples were not composited. Further, as noted in response to question number 1, Albaugh has provided what information it has obtained from Blackman Uhler with respect to the date and time the samples were collected by Blackman Uhler. Albaugh respectfully submits that the other information specified in this request regarding the retained samples is already set forth in section 7.3 of the proposed protocol.

7. "Detailed descriptions of the sampling procedures for obtaining all available retained samples and Manufacturing Work Task 17-001, MWT "DCP Drum Sampling Procedure" mentioned in Sect. 7.3.3. of the protocol must be resubmitted for an additional review by EPA and the Panel."

Response: See Paragraph 6, above. In addition, the document "Manufacturing Work Task 17-001, MWT "DCP Drum Sampling Procedure" is attached hereto (Att. 3).²

Further, at EPA's suggestion, Albaugh also is submitting an amendment to section 6.4 of the proposed protocol to reference the information in section 7.0 regarding the selection of the Test System (see Att. 2).

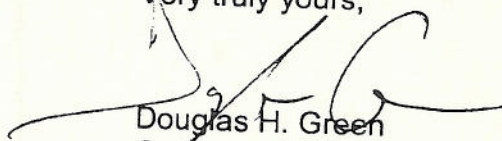
² Albaugh notes that the second page of this attachment is a table that should have been completed to document the sampling activity. Blackman Uhler has informed Albaugh that these tables were either not created or not retained.

8. Requested changes to specified sections of the protocol regarding "Justification for Selection of the Test System" and "Sampling Phase."

Response: Again, as noted above, Albaugh is submitting with this letter an amendment to section 7.3.3. of the proposed protocol to reflect the agitation process that occurred prior to the collection of the retained samples by Blackman Uhler. EPA has suggested that certain other amendments be made to portions of section 7 of the proposed protocol but has not indicated what those changes should be. Albaugh assumes that EPA's suggestion for further amendments is predicated on the assumption that there are additional samples to be referenced in the proposed protocol or that there is additional information available from Blackman Uhler regarding the retained samples that should be included in the protocol. As explained above, there are no additional samples and Albaugh is not aware of any additional information available from Blackman Uhler regarding the the retained samples (with the exception noted above of the amended section 7.3.3. of the protocol). If EPA has specific amendments in mind that it believes should be made to the above-referenced portions of the proposed protocol, Albaugh would be willing to incorporate those amendments into the proposed protocol if possible.

If you have further questions regarding the above information, please contact me or Stuart Feldstein at (515) 242-2405.³ On behalf of Albaugh, Inc., we look forward to a mutually satisfactory final resolution of this matter.

Very truly yours,

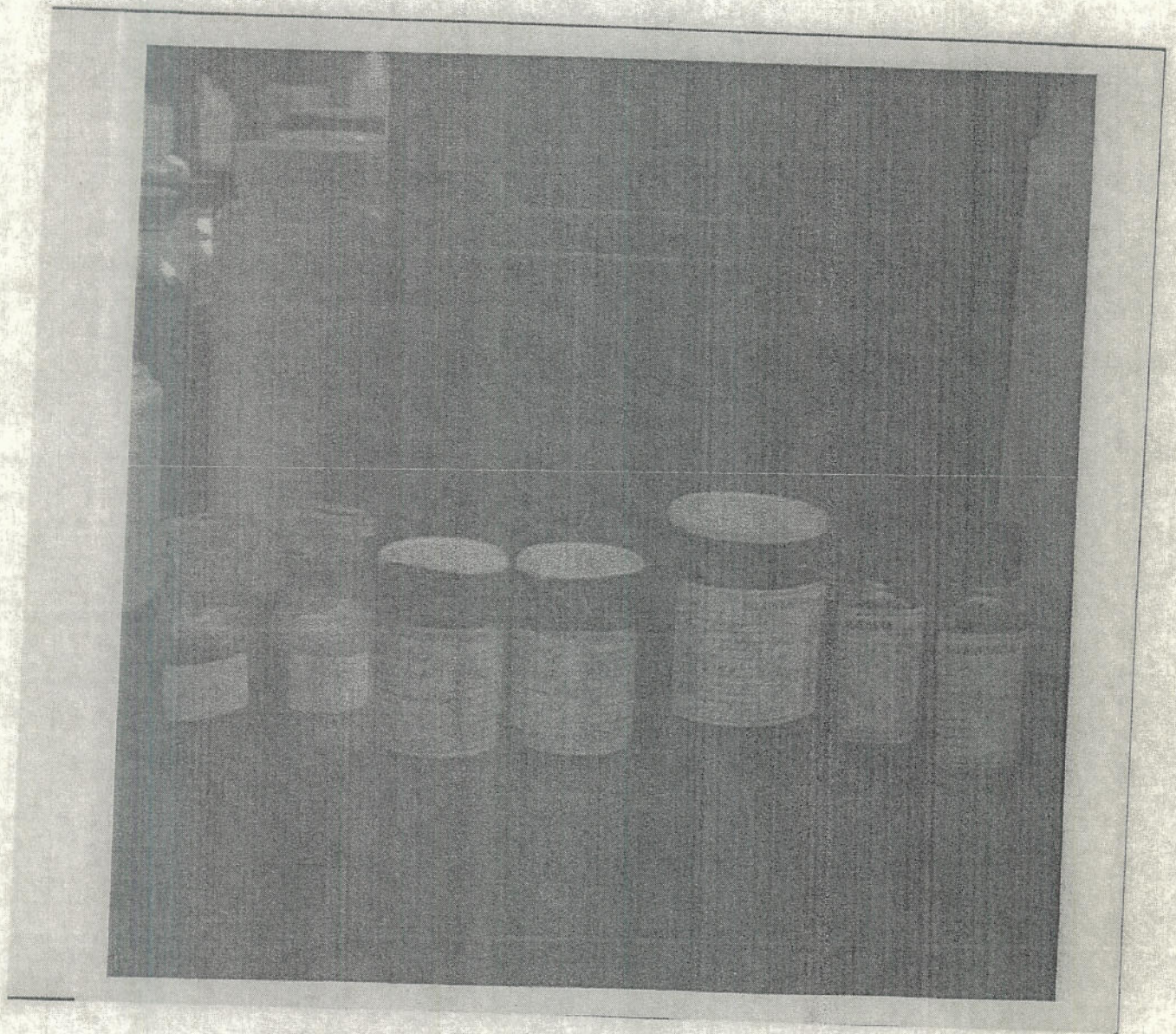


Douglas H. Green
On Behalf of Albaugh, Inc.

cc: Albaugh, Inc.
Stuart I. Feldstein
Mark Bauer, Battelle, Inc.
Charles M. Auer, EPA
David Williams, EPA
Mark Garvey, EPA
Oksana Pozda, EPA

³ In the future, Mr. Feldstein can be reached at the above number at the law firm of Brown, Winick, Graves, Gross, Baskerville, Schoenbaum, PLC., 666 Grand Avenue, Suite 2000, Des Moines, Iowa 50309.

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PROTOCOL AMENDMENT

Determination of Polychlorinated Dibenzo-p-dioxins and Dibenzofurans in Collected Samples of 2,5-Dichlorophenol

Protocol Amendment Number: 1

Effective Date: 1/15/04

ORIGINAL PROTOCOL INFORMATION:

Section 6.4 Justification for Selection of the Test System

The test system for this study is the same as the test substance upon which all analyses will be conducted. The test system chosen is the actual substance to which the Dioxin/Furan test Rule applies.

Section 7.3.3 Sampling Process, paragraph 2

The selected drum was placed in a steam cabinet at 120 °C for 24 hours to re-liquefy the material. The drums were not rolled; samples were taken from the bottom and top of a drum. The melting point of the test substance is 57 °C and has a viscosity of 5-10 cps. The drums were sampled with glass tubes approximately 3 feet long with rubber bulbs. The molten test substance was drawn up into the tube and transferred to glass containers of about 2-4 oz. in volume.

CHANGES/REVISIONS:

Section 6.4 Justification for Selection of the Test System

The test system for this study is the same as the test substance upon which all analyses will be conducted. The test system chosen is the actual substance to which the Dioxin/Furan test Rule applies. Additional information about the test system is included in Section 7, below.

Section 7.3.3 Sampling Process, paragraph 2

The selected drum was placed in a steam cabinet at 120 °C for 24 hours to re-liquify the material. The drums were removed from the steam cabinet with agitation to homogenize the drum contents. The melting point of the test substance is 57 °C and has a viscosity of 5-10 cps. The drums were sampled with glass tubes approximately 3 feet long with rubber bulbs. The molten test substance was drawn up into the tube and transferred to glass containers of about 2-4 oz. in volume.

REASONS FOR CHANGES

Section 6.4: EPA reviewer's request.

Section 7.3.3: Provide more accurate details about the sampling process.

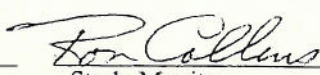
IMPACT ON STUDY:

All of the changes will have no impact on the study.

APPROVED BY:

Battelle Study Director

Date


Study Monitor

1/15/04
Date

PROTOCOL AMENDMENT

Determination of Polychlorinated Dibenzo-p-dioxins and Dibenzofurans in Collected Samples of 2,5-Dichlorophenol

Protocol Amendment Number: 1

Effective Date: 1/15/04

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REASONS FOR CHANGES

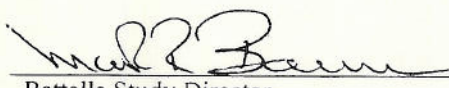
Section 6.4: EPA reviewer's request.

Section 7.3.3: Provide more accurate details about the sampling process.

IMPACT ON STUDY:

All of the changes will have no impact on the study.

APPROVED BY:

 1/15/04
Battelle Study Director Date

Study Monitor Date

3

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MANUFACTURING WORK TASK

PROCESS NAME: DCP DRUM SAMPLING PROCEDURE
DEPT. NO.: 1700
DATE OF ISSUE: 11/03/00
ISSUE NO.: 01

APPROVED BY: _____ (Product Development Mgr.)
APPROVED BY: _____ (Safety Manager)
APPROVED BY: _____ (Engineering rep.)
APPROVED BY: _____ (Department Supervisor)
ISSUED BY: _____ (Management Rep.)

CONTROLLED DOCUMENT NO.: 17-001.MWT

Color logo, current Rev. No. and Rev. Date identify authorized copy

NAME	DCP DRUM SAMPLING
CODE NO.	PROCEDURE
DEPT. NO.	17-001.MWT
LOC. NO.	1700
	N/A

DCP DRUM SAMPLING PROCEDURE

CODE NO.

17-001.MWT

DEPT. NO.

1700

LOC. NO.

N/A

ISSUE NO.	01
PAGE NO.	2 of 6
REV. DATE	11/03/00
REV. NO.	01

The following amendments have been approved and issued:

[illegible]

CONTROLLED DOCUMENT NO.: 17-001.MWT

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MANUFACTURING WORK TASK

NAME DCP DRUM SAMPLING
PROCEDURE
CODE NO. 17-001.MWT
DEPT. NO. 1700
LOC. NO. N/A

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Safety Warning:

The 2,5-Dichlorophenol may contain up to 5% 2,4-Dichlorophenol in its molten state has been reported to cause skin burns and small amounts of molten material can be rapidly absorbed through skin that can cause cardiac arrest and death. 2,5-Dichlorophenol should be regarded as having similar toxic effects in its molten state. Full protective body suits impervious to these materials together with a full face respirator, protective gloves and rubber boots must be worn at all times when sampling drums. The location of safety shower(s) in the immediate work area should be well known to any personnel sampling DCP drums. All safety precautions *must be observed* with these raw materials.
Note: Dichlorophenols are not soluble in water. Any exposed area of the body must be immediately scrubbed with plenty of soap and water!

Materials Needed:

1. Special glass pipettes (one per drum) from lab and rubber bulbs.
2. New sample bottles 2 to 8 ounce (the number of bottles will be determined by the supervisor) from the lab. Prelabel each bottle and cap with drum number (e.g. numbers 1 through 20 for 20 drums to be sampled) and lot number. Utilize preprinted labels and check highly toxic, irritant.
3. One gallon pail or similar container to hold the final sample bottle during sampling.
4. One 5-gallon pail for collecting all the samples in for lab.
5. A large marking pen or label with drum numbers to label drums as they are sampled.
6. Small plastic tight head drum (20 or 30 gallon) to put used pipettes. Drum should be properly labeled as "Used Sample Devices for Dichlorophenol". Continue to use this same drum for the pipettes and/or bottles until full then it will be sent off for Waste Disposal.

CONTROLLED DOCUMENT NO.: 17-001.MWT

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MANUFACTURING WORK TASK

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PROCEDURE
CODE NO. 17-001.MWT
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SAMPLING PROCEDURE

Dichlorophenol(s) should melt in the range of 46°C to 53°C.

STEP NO.	ACTION	NOTES, WARNINGS & CORRECTIVE ACTIONS
1	The drums should be on good pallets and placed in the Hot Box. The large bung on each drum must be loosened.	CAUTION: DCP will sublime up into the hotbox if the bungs are removed from the opening.
2	Allow at least 12 hours in the Hot Box at 95 - 110°C for the drum to completely melt. Monitor and check the Hot Box for overheating.	The DCP should not be heated longer than 16 hours before sampling since the material tends to darken on extended heating.
3	When ready to sample drums, wear all required protective clothing, etc. Get special glass sampling pipettes from the lab for sampling. These are to be used only once per drum (i.e. one pipette for each drum). Also, get new sample bottles from the lab and a gallon or similar container to put sample bottle in when sampling to trap any small spills from the pipette while transferring to bottle. Have a second container (1-gallon or 5-gallon pail) to transport sample bottles in after sampling.	CAUTION: Hot and Toxic. Wear impervious coveralls, such as tychem or Chem Tech 2, nitrile gloves, full face respirator with organic vapor cartridge and rubber boots.

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MANUFACTURING WORK TASK

NAME DCP DRUM SAMPLING
PROCEDURE
CODE NO. 17-001.MWT
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LOC. NO. N/A

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4	<p>To sample, carefully remove large bung.</p> <p>Using sample pipette, put rubber bulb over top of pipette and carefully insert into large bung opening. When pipette is about all the way down in the drum, hold at this position for 1 minute to allow pipette to warm to temperature of liquid then allow molten DCP to draw up into pipette bulb (about 1 minute). Quickly remove rubber bulb from pipette, place finger on top of pipette end, withdraw carefully from drum and let drain into sample jar. Dispose of pipette in a tight head waste drum through the large bung opening. Immediately seal sample bottle with cap while still in the gallon container.</p>	<p>NOTE: If any DCP gets into rubber bulb, discard into disposal drum.</p> <p><i>Do not clean off bottle of any liquid or solid DCP. Just place the sample bottle as is in designated container for lab.</i></p>
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STEP NO.	ACTION	NOTES, WARNINGS & CORRECTIVE ACTIONS
5	Replace large bung on drum and tighten down. Do not attempt to clean any spilled DCP liquid on drums. Report any spills immediately to supervisor.	
6	Mark the drum sampled with the same number as on the sample bottle.	

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MANUFACTURING WORK TASK

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When all the drums have been sampled, transfer the filled and closed sample jars to the 5-gallon pail to carry to the lab.

NOTE: Any spills should be absorbed with "Oil Absorbent" and transferred to a Waste Drum for disposal.

WITHOUT EXCEPTION, any exposure or skin contact with Dichlorophenol must be reported to the supervisor!

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